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10/562,716	01/23/2006	Yoshiyuki Ishikura	47237-5022-00 (412785)	9548

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EXAMINER	
VAKILI, ZOHREH	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,716	ISHIKURA ET AL.	
	Examiner	Art Unit	
	ZOHREH VAKILI	1614	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-48* is/are pending in the application.

4a) Of the above claim(s) *32-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-31,47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/3/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 17-48 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed September 1, 2010 has been received and entered into the present application. Claims 32-46 are withdrawn. Claims 17-31 and 47-48 are pending and are herein examined on the merits.

Claims 39-46 were included in all of the restriction groups in the Restriction mailed 10/15/2008, thus suggesting that could be interpreted as compositions, methods of treatment, or methods of preparation. Applicants have now amended the claims to recite a method of preparing a food or drink, which would place this method in Group II, which was not elected. Therefore, claims 39-46 are withdrawn from consideration due to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-31 and 47-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of administration of the omega-9 unsaturated fatty acid to a "patient in need thereof" renders the claims indefinite because the active method is not so linked to the preamble of the claim so as to clearly and unequivocally convey that a "patient in need thereof" is a patient in need of treating of liver diseases associated with hepatopathy, and not simply to a patient in need of the omega-9 unsaturated fatty acid. Applicants can overcome this rejection by amending the claims to recite administering to a "patient having a liver disease associated with hepatopathy".

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-31 and 47-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of the Invention: The claims are drawn to the method of ameliorating liver diseases associated with hepatopathy comprising administering an omega-9 unsaturated fatty acid.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass the use of compound of formula I, but fail to show how these fatty acids, for example, 6,9-octadecanoic acid (18:2 w9), 8,11-eicosadienoic acid (20:2 w9), and 5,8,11-eicosatrienoic acid (20:3 w9) are used for ameliorating liver diseases associated with hepatopathy

Guidance of the Specification: The guidance given by the specification is not

enabled for the full scope of the claimed invention based on the effects of a specific omega-9 fatty acid composition, i.e., a composition comprising 6,9-octadecanoic acid (18:2 w9), 8,11-eicosadienoic acid (20:2 w9), and 5,8,11-eicosatrienoic acid (20:3 w9) in a ratio of 12.94%, 3.29%, and 16.83% (see preparation method of Reference Example 1 and working examples 1 and 2 at pages 17-19) or a composition comprising 5,8,11-eicotrienoic acid ethyl ester (mead acid) (Example 3 at page 19). Further, Applicant's model of hepatopathy *induced by GalN/LPS* is not predictive of treating acute or chronic hepatitis, acute hepatic insufficiency, liver cirrhosis, and/or hepatoma.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to full scope of the claimed invention based on the effects of a specific omega-9 fatty acid composition would make practicing the claimed invention unpredictable in terms of treating acute or chronic hepatitis, acute hepatic insufficiency, liver cirrhosis, and/or hepatoma

Absent such evidence or reasoning, and further absent any direction or guidance as to how the skilled artisan would go about using the claimed compound of the claimed invention, treating acute or chronic hepatitis, acute hepatic insufficiency, liver cirrhosis, and/or hepatoma, one of ordinary skill in the art would have no alternative recourse but to undertake an exhaustive, and, thus, unduly burdensome, search for ways for the efficacy of the claimed invention suitable for use in practicing the claimed method, particularly since the skilled artisan is faced with such a breadth and variety of possible compositions from which to choose. In addition, it is not readily apparent that the prior art recognized methods of treating acute or chronic hepatitis, acute hepatic

insufficiency, liver cirrhosis, and/or hepatoma with the presently claimed compound at the time of the invention (or at least Applicant has failed to point to such information in a document that can be properly incorporated by reference) such that one of ordinary skill in the art would have been able to drawn upon the knowledge already present in the prior art to execute the treatment of acute or chronic hepatitis, acute hepatic insufficiency, liver cirrhosis, and/or hepatoma with the presently claimed compound absent factual evidence to the contrary.

Applicant has (1) failed to provide any clear correlation of such disclosed general procedures to the instantly claimed compound or (2) failed to provide any working or prophetic examples directed to a possible method and/or manner of treating acute or chronic hepatitis, acute hepatic insufficiency, liver cirrhosis, and/or hepatoma for the instantly claimed compound. While the lack of a working embodiment cannot be the *sole* factor in determining enablement, the absence of substantial evidence commensurate in scope with the breadth of the presently claimed subject matter, in light of the unpredictable nature of the art and the limited direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test

of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue.*" (emphasis added)

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a MD, PHD or scientist with several years of experience in the art.

As the discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation or ability to make the full scope of the invention as instantly claimed, given the disclosure and supporting examples provided in the present specification at the time of the invention. In order to actually achieve the claimed invention, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the embodiments presently claimed.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-31 and 47-48 are rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabled for the process obtaining a fatty acid by culturing Mortirella alpina mutant strains SAM 1861 or SAM 2086, does not reasonably provide enablement for obtaining a fatty acid by other culturing method as broadly claimed in claims 21, 28, and 43. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connect, to make the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The presently claimed invention is directed to a method of ameliorating liver disease associated with hepatopathy comprising administering an omega-9 unsaturated fatty acid.

However, the instant specification as originally filed lacks adequate guidance,

direction or discussion to apprise the skilled artisan of the specific conditions and/or starting materials and/or reaction schema to be used to obtain the claimed compounds. In the absence of such direction or guidance, the instant specification fails to provide adequate enabling disclosure to practice the full scope of the claimed subject matter.

The steps be introduced and eliminated according to conventional methods used in extraction, separation, and purification of the free omega-9 unsaturated fatty acid. In such processes, if the defined steps change under the conditions of the working method or are not appropriate for carrying out the method, the desired compound can be obtained by using the methods for introducing and eliminating steps which are conventionally used in organic chemistry. Culturing of microorganisms can be carried out by known methods.

However, while such disclosure has been fully and carefully considered, it is noted that this same disclosure lacks a clear teaching, direction or guidance as to how to prepare compounds of the instantly claimed invention

Furthermore, it is noted that the execution of chemical reactions, extraction, separation, purification is dependent upon numerous variable factors that are essential for producing the intended compound, such as, but not limited to, the starting materials to be employed, the temperature at which the reaction(s) should be carried out, solvents, reaction catalysts, molar quantities, surface area, pressure, activation energies, etc. In view of such a number of factors, and further in view of the high degree of variability for each single factor that must be taken into account in order to provide an accurate means for producing the claimed compounds, the state of the art

with regard to chemical reactions in general is highly complex and sufficiently unpredictable such that the skilled artisan would have been required to undertake undue experimentation to determine the exact conditions and manner and/or process of execution to arrive at those conditions that would have been amenable to actually producing the compound as claimed in the absence of detailed guidance to this effect.

Absent such evidence or reasoning, and further absent any direction or guidance as to how the skilled artisan would go about synthesizing the claimed compound of the claimed invention one of ordinary skill in the art would have no alternative recourse but to undertake an exhaustive, and, thus, unduly burdensome, search for ways to synthesize this embodiment of the claimed invention suitable for use in practicing the claimed method, particularly since the skilled artisan is faced with such a breadth and variety of possible starting materials and reaction schema from which to choose. In addition, it is not readily apparent that the prior art recognized methods of synthesizing the presently claimed compound at the time of the invention (or at least Applicant has failed to point to such information in a document that can be properly incorporated by reference) such that one of ordinary skill in the art would have been able to drawn upon the knowledge already present in the prior art to execute the synthesis of the presently claimed compound absent factual evidence to the contrary.

Applicants demonstrate culturing Mortierella alpine mutant strains SAM 1861 or SAM 2086 in a medium (pH 6.0) containing glucose and 1% yeast extracts. How does this enable one skilled in the art to obtain the triglyceride having an omega-9 fatty acids by culturing "a microorganism" in "a medium" as broadly recited in claims 21, 28, and

43? Applicant has (1) failed to provide any clear correlation of such disclosed general culturing procedures to the instantly claimed compound or (2) failed to provide any working or prophetic examples directed to a possible method and/or manner of extraction, separation, and purification for the instantly claimed compound. While the lack of a working embodiment cannot be the *sole* factor in determining enablement, the absence of substantial evidence commensurate in scope with the breadth of the presently claimed subject matter, in light of the unpredictable nature of the art and the limited direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added)

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a PHD or scientist with several years of experience in the art.

As the discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation or ability to make the full scope of the invention as instantly claimed, given

the disclosure and supporting examples provided in the present specification at the time of the invention. In order to actually achieve the claimed invention, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the embodiments presently claimed.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 17, 20-31 and 47-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals compounds such as omega-9 unsaturated fatty acid, which meet the written description and enablement provisions of 35 USC 112, first paragraph.

However, claims 17-31 and 47-48 are directed to encompass compounds having an omega-9 unsaturated fatty acid as a constituent fatty acid, which only corresponds in some undefined way to specifically instantly disclosed chemicals. None of these constituent fatty acids, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed constituent fatty acids, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he

description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-20, 22-27, 29-31, and 47-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, and 9 of U.S. Patent No. 5981588 B1 (Akimoto et al., Issued Nov. 1999).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

In this case, the patented claims recite claims preventing or alleviating medical symptoms caused by delayed allergy reaction comprising administering an omega-9 fatty acid (claim 1), wherein the medical symptom results from a delayed allergy reaction in a disease selected from, inter alia, hepatitis (claim 3). Such subject matter of the present claims directly conflicts with the subject matter of the patent and is not considered to be patentably distinct.

Thus, claims 17-20, 22-27, 29-31, and 47-48 are not considered to be patentably distinct over claims 1-3, 5, 6, and 9 of U.S. Patent No. 6685953 B1, and are properly rejected under the judicially created doctrine of obviousness-type double patenting as being obvious and unpatentable variants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-31 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto et al. (USPN 5981588) (cited on IDS filed 3/26/2007).

Akimoto et al. teach a method for preventing or alleviating medical symptoms caused by delayed allergy reaction comprising administering to a patient an Omega 9-unsaturated fatty acid (claim 1). A method for preventing or alleviating medical symptoms according to claim 1, wherein the .omega.9-unsaturated fatty acid is selected from the group consisting of 6,9-octadecadienoic acid, 8,11-eicosadienoic acid and 5,8,11-eicosatrienoic acid (claim 2). A method for preventing or alleviating

medical symptoms according to claim 1, wherein the medical symptom results from a delayed allergy reaction in a disease selected from the group consisting of autoimmune diseases, Inter alia, hepatitis (claim 3).

Omega.9-unsaturated fatty acids of the present invention may be used in a form of mono-, di- or triglycerides. These may be used alone or in any combination (col. 2, line 33). An administration dose varies depending on the purpose of administration and the conditions (sex, age, body weight, etc.) of the patient, but generally, where the fatty acid is orally administered to an adult human, its daily dose is 1 mg to 10 g (col. 4, lines 2-6). As microorganisms capable of producing omega 9-unsaturated fatty acids, there may be used microorganisms having DELTA 5 desaturase activity and DELTA 6 desaturase activity, and having reduced or no DELTA 12 desaturase activity, such as Mortierella alpina SAM1861 (FERM BP-3590). Mortierella alpina SAM 1861 (FERM BP-3590) (col. 2, lines 49-55). The food product may be in the form of a solid, liquid or any other type of preferred food, for example drinks such as juices, soft drinks, sports drinks; or the like (col. 4, lines 57-67).

It would have been obvious to have used Akimoto et al. to produce a method of ameliorating liver diseases administering omega-9 unsaturated fatty acid.
One of ordinary skill in the art would have been motivated to use the teachings of the above reference and suggest the invention as claimed. Akimoto et al. teaches the same composition and method with the same mechanism and overlapping dosage range to be used for the same purpose as the claimed invention. The determination of the optimum ranges for the presently claimed active agent(s) would have been a

matter well within the purview of one of ordinary skill in the art. Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Finally, one would have a reasonable expectation of success given that the above reference provides a detailed blueprint for a method of ameliorating liver diseases administering omega-9 unsaturated fatty acid, and the steps of which are routine to one of ordinary skill in the art.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Response to Argument

Applicant's arguments and remarks are moot in view of new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 9:00-6:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614 December 14, 2010

/James D Anderson/

Primary Examiner, Art Unit 1614